

warnings under the “Warnings” heading. (i) “Do not use on children under 2 years of age.” (This warning is to be used in place of the warning in paragraph (c)(1)(i) of this section.)

(ii) “Do not use for diaper rash.”

(d) *Directions*. The labeling of the product contains the following statements under the heading “Directions”:

(1) *For products labeled according to paragraph (b)(1) of this section for the treatment of athlete’s foot, jock itch, and ringworm*. [Select one of the following: “Clean” or “Wash”] “the affected area and dry thoroughly. Apply” (the word “spray” may be used to replace the word “apply” for aerosol products) “a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete’s foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete’s foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.”

(2) *For products labeled according to paragraph (b)(2) of this section for the prevention of athlete’s foot*. “To prevent athlete’s foot,” (select one of the following: “clean” or “wash”) “the feet and dry thoroughly. Apply” (the word “spray” may be used to replace the word “apply” for aerosol products) “a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.”

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

EFFECTIVE DATE NOTE: At 67 FR 52305, Aug. 29, 2000, § 333.250 was amended by revising the introductory texts of paragraphs (b)(1)(i) and (b)(2)(i) and by revising paragraph (b)(2)(ii), effective May 16, 2002. For the convenience of the user, the revised text is set for as follows:

(b) * * *

(1) * * * (i) (Select one of the following: “Treats,” “For the treatment of,” “For effective treatment of,” “Cures,” “For the cure of,” “Clears up,” or “Proven clinically effective in the treatment of”) “most” (select one condition from any one or more of the following groups of conditions:

* * * * *

(2) * * * (i) (Select one of the following: “Clinically proven to prevent,” “Prevents,” “Proven effective in the prevention of,” “Helps prevent,” “For the prevention of,” “For the prophylaxis (prevention) of,” “Guards against,” or “Prevents the recurrence of”) “most” (select one of the following: “Athlete’s foot,” “athlete’s foot (dermatophytosis),” “athlete’s foot (tinea pedis),” or “tinea pedis (athlete’s foot)”) “with daily use.”

(ii) In addition to the information identified in paragraph (b)(2)(i) of this section, the labeling of the product may contain the following statement: “Clears up most athlete’s foot infection and with daily use helps keep it from coming back.”

§ 333.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following additional indication:

(a) *For products containing haloprogin or miconazole nitrate identified in § 333.210 (a) and (c)*. “For the treatment of superficial skin infections caused by yeast (*Candida albicans*).”

(b) [Reserved]

Subpart D—Topical Acne Drug Products

SOURCE: 56 FR 41019, Aug. 16, 1991, unless otherwise noted.

§ 333.301 Scope.

(a) An over-the-counter acne drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.303

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§ 333.303 Definitions.

As used in this subpart:

(a) *Acne*. A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes.

(b) *Acne blemish*. A flaw in the skin resulting from acne.

(c) *Acne drug product*. A drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads.

(d) *Acne pimple*. A small, prominent, inflamed elevation of the skin resulting from acne.

(e) *Blackhead*. A condition of the skin that occurs in acne and is characterized by a black tip.

(f) *Whitehead*. A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin.

§ 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following when labeled according to § 333.350.

(a) Resorcinol 2 percent when combined in accordance with § 333.320(a).

(b) Resorcinol monoacetate 3 percent when combined in accordance with § 333.320(b).

(c) Salicylic acid 0.5 to 2 percent.

(d) Sulfur 3 to 10 percent.

(e) Sulfur 3 to 8 percent when combined in accordance with § 333.320.

§ 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(a) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

(b) Resorcinol monoacetate identified in § 333.310(b) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

§ 333.350 Labeling of acne drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “acne medication,” “acne treatment,” “acne medication” (insert dosage form, *e.g.*, “cream,” “gel,” “lotion,” or “ointment”), or “acne treatment” (insert dosage form,

e.g., “cream,” “gel,” “lotion,” or “ointment”).

(b) *Indications*. The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section and may contain any of the additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) “For the” (select one of the following: “management” or “treatment”) “of acne.”

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any one or more of the following statements:

(i) (Select one of the following: “Clears,” “Clears up,” “Clears up most,” “Dries,” “Dries up,” “Dries and clears,” “Helps clear,” “Helps clear up,” “Reduces the number of,” or “Reduces the severity of”) (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”) which may be followed by “and allows skin to heal.”

(ii) “Penetrates pores to” (select one of the following: “eliminate most,” “control,” “clear most,” or “reduce the number of”) (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”).

(iii) “Helps keep skin clear of new” (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”).

(iv) “Helps prevent new” (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”) which may be followed by “from forming.”

(v) “Helps prevent the development of new” (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”).

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) *For products containing any ingredient identified in § 333.310.* (i) “For external use only.”

(ii) “Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.”

(2) *For products containing sulfur identified in §§ 333.310 (d) and (e).* “Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor.”

(3) *For products containing any combination identified in § 333.320.* “Apply to affected areas only. Do not use on broken skin or apply to large areas of the body.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) “Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.”

(2) The directions described in paragraph (d)(1) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks, may be applied and removed and should have appropriate directions.

(3) *Optional directions.* In addition to the required directions in paragraphs (d)(1) and (d)(2) of this section, the product may contain the following optional labeling: “*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated: (se-

lect one of the following: ‘elsewhere on this label,’ ‘above,’ or ‘below.’)”

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 52 FR 15892, Apr. 30, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 336.1 Scope.

(a) An over-the-counter antiemetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 336.3 Definition.

As used in this part:

Antiemetic. An agent that prevents or treats nausea and vomiting.

Subpart B—Active Ingredients

§ 336.10 Antiemetic active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § 336.50(d):

(a) Cyclizine hydrochloride.

(b) Dimenhydrinate.

(c) Diphenhydramine hydrochloride.